REMARKS

Claim Status

Claims 1 – 5, 10, and 12 - 16 are pending in the present application. No additional claims fee is believed to be due.

Claims 8 and 9 are canceled without prejudice. Claims 6, 7, and 11 were previously canceled without prejudice.

Claim 1 has been amended to add the groups of polymers. Support for the amendment is found in original Claims 8 and 9.

In addition, new Claim 16 has been added. Support for this amendment is found in original Claim 1.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Rejections Under 35 USC §103(a)

I. Claims 1-5, 8-10 and 12-15 are rejected under 35 USC §103(a) as being unpatentable over US Patent Application No. 2001/0044410 to Gelber ("Gelber") in view of US Patent Application No. 2004/0077601 to Adams ("Adams") in view of US Patent No. 5,158,761 to Kamishita ("Kamishita"), and further in view of US Patent No. 6,294,168 to Beerse et al. ("Beerse").

The Examiner asserts that Gelber teaches a method and compositions that treats a condition caused by an immune response to a virus, that the aqueous saline solution can be applied by a spray administered to the nasal mucosa. The Examiner asserts that Gelber discloses the Applicants' preferred ingredients, and that the pH of the composition of Gelber would inherently be about 3.0 to about 5.5 because Gelber teaches ascorbic acid. The Examiner also asserts that Gelber discloses the Applicants' claimed range for zinc gluconate and ascorbic acid. The Examiner acknowledges that Gelber does not teach a method for treating SARS, nor a composition comprising an mucoadhesive polymer, nor a viscosity of from about 1 cps to about 2000 cps, a sensate, or a pH adjusting agent.

However, the Examiner asserts that Adams teaches a method of stimulating an immune response of a viral infection such as SARS, and that the method may be delivered in the form of an aerosol spray mucosally to the nose.

The Examiner asserts that Kamishita teaches a spray base gel composition comprising an aqueous solution of carboxyvinyl polymer with a water soluble basic substance with a viscosity within the range of 500 – 5000 cps. The Examiner asserts that Kamishita teaches that the pH value of the gel is adjusted with a water-soluble basic substance. The Examiner asserts that Kamishita teaches thickeners such as those of Claims 1 and 8. The Examiner also asserts that Kamishita teaches a pH range of 4-9, that the preparation is applied to mucus membranes in the nasal cavity, and that the preparation is useful in a clinical use such as an influenza vaccine.

Additionally, the Examiner asserts that Beerse teaches antimicrobial compositions comprising an effective amount of a benzoic acid analog, a metal salt, and a dermatologically acceptable carrier, wherein the pH of the composition is from about 1 to about 7. The Examiner asserts that the method is used to treat the area of the nose, nasal canal, or passage. The Examiner also asserts that Beerse teaches thickeners such as those of Claims 1, 8, and 9. The Examiner asserts that various skin sensates are taught by Beerse.

Therefore, the Examiner asserts that one of ordinary skill in the art at the time of the invention, based on the teachings of the cited documents, would have found it obvious, and be motivated, to combine the method of Gelber with the method of Adams to treat SARS because Gelber teaches compositions to treat viral infections, and that SARS is a respiratory infection caused by a virus.

The Examiner asserts that it would have been obvious to combine the composition of Gelber with a viscosity of from about 1 cps to about 2000 cps, and a pH adjusting agent because both Kamishita and Gelber teach aqueous nasal spray respiratory anti-viral compositions and methods, and because Kamishita teaches a composition having a pH of 4-7, viscosity of 500 to 5000 cps, cellulose polymers, and a pH adjuster. The Examiner asserts that the motivation to combine is found because having a composition comprising a pH adjuster and viscosity of 1 cps to 2000 cps would increase efficacy of the spray to treat SARS by providing excellent spray base properties. The Examiner asserts that obviousness exists when ranges of a claimed composition overlap the ranges disclosed in the art, and that it is normal for scientists or artisans to want to improve upon what is

known. The Examiner cites case law for the assertion that discovery of an optimum value of the result effective variable in a known process is ordinarily within the skill of the art.

The Examiner further asserts that it would have been obvious, and that one of skill in the art would have been motivated, to combine Gelber with a sensate because both Gelber and Beerse teach a metal salt composition to treat viral conditions and that can be applied nasally, that Beerse teaches a wide variety of cosmetic and pharmaceutical ingredients such as skin sensates, and that Beerse teaches levels of skin sensates. The Examiner asserts that motivation to combine the sensate is found because sensates are commonly used in personal care for a patient's perceived sensation, and is used in anti-viral compositions as taught by Beerse.

The Examiner also asserts that it would have been obvious to combine the composition of Gelber with a mucoadhesive polymer because Kamishita, Beerse, and Gelber all teach aqueous, nasal anti-viral compositions and methods; Kamishita teaches cellulose polymers; Beerse teaches thickeners; and that although the 'thickeners' of Beerse are not labeled as thermoreversible polymers hydroxyethyl ethyl cellulose is disclosed and that products of identical chemical composition can not have mutually exclusive properties. Thus, the Examiner asserts that the use of thermoreversible polymers of Claims 8 and 9 are known in the art as taught by Kamishita and Beerse.

The Applicants respectfully traverse the rejection. The Examiner has not established a *prima facie* case of obviousness because the cited documents, when considering the Claims and the claimed invention as a whole, do not teach or suggest all of the claim limitations of the rejected Claims. See MPEP 2143.03.

Specifically, Gelber discloses a composition that includes an effective amount of a pain relieving and anti-inflammatory pharmaceutical. Gelber fails to teach or suggest a method of treating SARS by administering a nasal respiratory tract composition having a pH of from about 3.0 to about 5.5 to areas of the upper respiratory tract, wherein the respiratory tract composition comprises: from about 0.01% to about 10% by weight of an organic acid; from about 0.01% to about 20% by weight of a metal compound comprising a metal ion selected from the group consisting of manganese(Mg), silver (Ag), zinc (Zn), tin (Sn), iron (Fe), copper (Cu), aluminum (Al), nickel (Ni), cobalt (Co), or mixtures thereof; from about 0.01% to about 30% by weight of a mucoadhesive polymer selected from the group consisting of hydroxypropyl methylcelluloses, hydroxypropyl celluloses, methyl cellulose

polymers, carboxymethyl cellulose polymers, salts of carboxymethyl cellulose, and mixtures thereof and thermoreversible polymers selected from the group consisting of poloxamers, ethylhydroxy ethylcelluloses, and mixtures thereof; wherein the composition has a viscosity of from about 1 cps to about 2000 cps. The Examiner states that Example disclosed in paragraph 73 discloses the amount of zinc gluconate and ascorbic acid. However, this example describes a composition administered in liquid form not a nasal composition.

Adams discloses a method for treating a subject in need with the Formula I described in the specification in an amount to inhibit abnormal mammalian cell proliferation and thereby inhibit the condition. Additionally, Adams discloses a method for stimulating an immune response in a subject comprising administering an agent of Formula I and an antibody or antibody fragment. Adams fails to teach or suggest a method of treating SARS by administering a nasal respiratory tract composition having a pH of from about 3.0 to about 5.5 to areas of the upper respiratory tract, wherein the respiratory tract composition comprises: from about 0.01% to about 10% by weight of an organic acid; from about 0.01% to about 20% by weight of a metal compound comprising a metal ion selected from the group consisting of manganese(Mg), silver (Ag), zinc (Zn), tin (Sn), iron (Fe), copper (Cu), aluminum (Al), nickel (Ni), cobalt (Co), or mixtures thereof; from about 0.01% to about 30% by weight of a mucoadhesive polymer selected from the group consisting of hydroxypropyl methylcelluloses, hydroxypropyl celluloses, methyl cellulose polymers, carboxymethyl cellulose polymers, salts of carboxymethyl cellulose, and mixtures thereof and thermoreversible polymers selected from the group consisting of poloxamers, ethylhydroxy ethylcelluloses, and mixtures thereof; wherein the composition has a viscosity of from about 1 cps to about 2000 cps.

The Examiner states that Adams teaches an aerosol spray mucosally to the nose on page 40 and 41. However, on page 39, paragraph 0349 discloses that administration by inhalation is for lung tumors. The disclosure in paragraph 0361 describes administration by inhalation which as already described is for treating lung tumors and paragraph 364 describes the administration of antibodies and antigens mucosally. Line 8, page 41 is describing the route of infection of antigens i.e. mucosal surfaces such as oral, nasal,

vaginal, penile and rectal, and has nothing to do with a method of treating SARS by administering a nasal respiratory tract composition having a pH of from about 3.0 to about 5.5 to areas of the upper respiratory tract.

Assuming *arguendo* that one having ordinary skill in the art would combine the disclosures of Gelber, and Adams, one would still fall short of the of Applicants' claimed invention only to arrive at a method of treating lung cancer comprising a composition that includes an effective amount of a pain relieving and anti-inflammatory pharmaceutical where the route of infection of an antigen is mucosal surfaces such as oral, nasal, vaginal, penile and rectal.

Gelber and Adams, alone or in combination, do not teach or suggest all of the claim limitations of Claims as pending, or the invention as a whole, and therefore, do not establish a *prima facie* case of obviousness (see MPEP 2143.03).

Kamishita discloses and requires the combination of a carboxyvinyl polymer with a water-soluble substance. Kamishita fails to teach or suggest about 0.01% to about 30% by weight of a mucoadhesive polymer selected from hydroxypropyl methylcelluloses, hydroxypropyl celluloses, methyl cellulomixtures thereof and thermoreversible polymers selected from the group consisting of poloxamers, ethylhydroxy ethylcelluloses, and mixtures thereof where the composition has a viscosity of from about 1 cps to about 2000 cps. Additionally, Kamishita does not cure the lack of disclosure to a method of treating SARS by administering a nasal respiratory tract composition having a pH of from about 3.0 to about 5.5 to areas of the upper respiratory tract, wherein the respiratory tract composition comprises: from about 0.01% to about 10% by weight of an organic acid; from about 0.01% to about 20% by weight of a metal compound comprising a metal ion selected from the group consisting of manganese(Mg), silver (Ag), zinc (Zn), tin (Sn), iron (Fe), copper (Cu), aluminum (Al), nickel (Ni), cobalt (Co).

Assuming *arguendo* that one having ordinary skill in the art would combine the disclosures of Gelber, Adams, and Kamishita, one would still fall short of the Applicants' claimed invention only to arrive at a method of treating lung cancer comprising a

composition that includes an effective amount of a pain relieving and anti-inflammatory pharmaceutical, 0.2-1.5% carboxyvinyl polymer, and a water-soluble substance, where the route of infection of an antigen is mucosal surfaces such as oral, nasal, vaginal, penile and rectal.

Gelber, Adams, and Kamishita, alone or in combination do not teach or suggest all of the claim limitations of Claims as pending, and the invention as a whole, and therefore, do not establish a *prima facie* case of obviousness (see MPEP 2143.03).

Beerse fails to teach or suggest a method of treating SARS by administering a nasal respiratory tract composition having a pH of from about 3.0 to about 5.5 to areas of the upper respiratory tract, wherein the nasal respiratory tract composition comprises: from about 0.01% to about 10% by weight of an organic acid; from about 0.01% to about 20% by weight of a metal compound comprising a metal ion selected from the group consisting of manganese(Mg), silver (Ag), zinc (Zn), tin (Sn), iron (Fe), copper (Cu), aluminum (Al), nickel (Ni), cobalt (Co), or mixtures thereof; from about 0.01% to about 30% by weight of a mucoadhesive polymer selected from polymeric cellulose derivatives selected from the group consisting of hydroxypropyl methylcelluloses, hydroxypropyl celluloses, methyl cellulose polymers, carboxymethyl cellulose polymers, salts of carboxymethyl cellulose, and mixtures thereof and thermoreversible polymers selected from the group consisting of poloxamers, ethylhydroxy ethylcelluloses, and mixtures thereof; and wherein the composition has a viscosity of from about 1 cps to about 2000 cps.

Beerse does not teach or suggest that the compositions disclosed therein would be effective against SARS. Nor does Beerse teach, suggest or provide motivation for the particular composition of the present invention. Furthermore, the Examiner relies on Beerse for inclusion of a sensate. Claim 1, as amended, does not recite a sensate.

Assuming *arguendo* that one having ordinary skill in the art would combine the disclosures of Gelber, Adams, Kamishita, and Beerse, one would still fall short of the Applicants' claimed invention only to arrive at a method of treating lung cancer

comprising a composition that includes an effective amount of a pain relieving and anti-inflammatory pharmaceutical, 0.2-1.5% carboxyvinyl polymer, a skin sensate, and a water-soluble substance, where the route of infection of an antigen is mucosal surfaces such as oral, nasal, vaginal, penile and rectal.

Gelber, Adams, Kamishita, and Beerse, alone or in combination do not teach or suggest all of the claim limitations of Claims as pending and the invention as a whole. Therefore, the cited documents do not establish a *prima facie* case of obviousness (see MPEP 2143.03). The Claimed invention must be taken as a whole. Because certain separate, individual elements may be known is not sufficient to establish obviousness. There must be some teaching, suggestion, motivation, and expectation of success that would have led one of skill in the art to combine all cited documents. The combination of Gelber, Adams, Kamishita, and Beerse does not teach or suggest each and every element of Applicants' presently claimed invention, nor provide motivation or expectation of success for the claimed invention as a whole, i.e. method of treating SARS by administering a nasal respiratory tract composition having a pH of from about 3.0 to about 5.5 to areas of the upper respiratory tract, wherein the respiratory tract composition comprises: from about 0.01% to about 10% by weight of an organic acid; from about 0.01% to about 20% by weight of a metal compound comprising a metal ion selected from the group consisting of manganese(Mg), silver (Ag), zinc (Zn), tin (Sn), iron (Fe), copper (Cu), aluminum (Al), nickel (Ni), cobalt (Co), or mixtures thereof; from about 0.01% to about 30% by weight of a mucoadhesive polymer selected from the group consisting of hydroxypropyl methylcelluloses, hydroxypropyl celluloses, methyl cellulose polymers, carboxymethyl cellulose polymers, salts of carboxymethyl cellulose, and mixtures thereof and thermoreversible polymers selected from the group consisting of poloxamers, ethylhydroxy ethylcelluloses, and mixtures thereof; wherein the composition has a viscosity of from about 1 cps to about 2000 cps.

Accordingly, Claims 1-5, 10, and 12-16 are novel and nonobvious over the prior art of record. Reconsideration and withdrawal of the rejection on this basis are requested.

II. Claim 9 is rejected as being unpatentable over Gelber in view of Adams, in view of Kamishita, and further in view of Beerse, as applied to Claims 1-5, 8-10, and 12-15 above, and further in view of US Patent No. 6,017,513 to Betbeder et al. ("Betbeder").

The Examiner acknowledges that none of Gelber, Adams, Kamishita, or Beerse teaches a composition comprising the mucoadhesive polymer as a thermoreversible polymer being polaxamers form about 0.01% to about 20% by weight.

The Examiner asserts that Betbeder teaches the use of an amphiphilic compound such as polaxamers, modified polyoxyethylene and other surface active compounds for use in a nasal mucosal administration to reduce the effect of a virus infection.

Thus, the Examiner asserts that it would have been obvious to combine the methods and compositions of Gelber, Adams, Kamishita, and Beerse with mucoadhesive polymers selected from the group consisting of polaxamers from about 0.01 to about 20% by weight. The Examiner asserts that Betbeder teaches the use of amphiphilic compounds such as polaxamers; Kamishita teaches the use of mucoadhesive polymers; Beerse teaches an anti-viral composition comprising about 0.01% to about 10% of one or more thickeners; poloxamers, ethylhydroxy ethylcelluloses, PVP, carboxyvinyl polymers, and hydroxypropyl methylcellulose are all mucoadhesive polymers; mucoadhesive polymers are known in the art to be used in nasal compositions; and products of identical composition can not have mutually exclusive properties. Citing *In re Spada*, the Examiner asserts that if the prior art teaches the identical chemical structure, the properties the applicant discloses and/or claims are necessarily present.

Therefore, the Examiner asserts that one would be motivated to combine Gelber, Adams, Kamishita, and Beerse because mucoadhesive polymers are known in the art to be used in nasal compositions as shown by Kamishita. The Examiner asserts that Betbeder demonstrates that a specific poloxamer is used to confer a particular physio-chemical environment, the mode of mucosal administration, and the desired effect. Thus, the Examiner asserts that one of skill in the art would be able to choose the appropriate mucoadhesive polymer for the composition.

The Applicants respectfully traverse the rejection. The Examiner has not established a *prima facie* case of obviousness because the cited documents, when considering the Claims and the claimed invention as a whole, do not teach or suggest all of the claim limitations of the rejected Claims. See MPEP 2143.03.

Betbeder fails to teach or suggest a method of treating SARS by administering a nasal respiratory tract composition having a pH of from about 3.0 to about 5.5 to areas of the upper respiratory tract, wherein the nasal respiratory tract composition comprises: from about 0.01% to about 10% by weight of an organic acid; from about 0.01% to about 20% by weight of a metal compound comprising a metal ion selected from the group consisting of manganese(Mg), silver (Ag), zinc (Zn), tin (Sn), iron (Fe), copper (Cu), aluminum (Al), nickel (Ni), cobalt (Co), or mixtures thereof; from about 0.01% to about 30% by weight of a mucoadhesive polymer selected from polymeric cellulose derivatives selected from the group consisting of hydroxypropyl methylcelluloses, hydroxypropyl celluloses, methyl cellulose polymers, carboxymethyl cellulose polymers, salts of carboxymethyl cellulose, and mixtures thereof and thermoreversible polymers selected from the group consisting of poloxamers, ethylhydroxy ethylcelluloses, and mixtures thereof; and wherein the composition has a viscosity of from about 1 cps to about 2000 cps.

The Applicants assert that the arguments presented above regarding Gerber in view of Adams, further in view of Kamishita, and further in view of Beerse, in traversing the § 103(a) rejection also apply to the present rejection. Additionally, the limitations of Claim 9 have been amended into Claim 1. Thus, the arguments herein with respect to Betbeder apply to Claim 1, as amended.

Betbeber et al. discloses the use of amphiphilic compounds for coating an outer layer of the core partially or wholly. The amphiphilic compound preferably mainly comprises natural or synthetic phospholipids or ceramide. The amphiphilic coating may also comprise poloxamers and modified polyoxyethylene. Betbeber et al does not teach or suggest a composition comprising from about 0.01% to about 30% by weight of a mucoadhesive polymer selected from hydroxypropyl methylcelluloses, hydroxypropyl celluloses, methyl cellulose polymers, carboxymethyl cellulose polymers, salts of carboxymethyl cellulose, and mixtures thereof and thermoreversible polymers selected from the group consisting of poloxamers, ethylhydroxy ethylcelluloses, and mixtures thereof.

Assuming *arguendo* that one having ordinary skill in the art would combine the disclosures of Gelber, Adams, Kamishita, Beerse, and Betbeder, one would still fall short of the of Applicants' claimed invention only to arrive at a method of treating lung cancer comprising a composition that is coated with an amphiphilic coating that may comprise poloxamers and modified polyoxyethylene, wherein the composition includes an effective amount of a pain relieving and anti-inflammatory pharmaceutical, 0.2-1.5% carboxyvinyl polymer, a skin sensate, and a water-soluble substance, where the route of infection of an antigen is mucosal surfaces such as oral, nasal, vaginal, penile and rectal.

Gelber, Adams, Kamishita, Beerse, and Betbeder, alone or in combination, do not teach or suggest all of the claim limitations of Claims as pending and the invention as a whole. Therefore, the cited documents do not establish a *prima facie* case of obviousness (see MPEP 2143.03). The Claimed invention must be taken as a whole. Because certain separate, individual elements may be known is not sufficient to establish obviousness. There must be some teaching, suggestion, motivation, and expectation of success that would have led one of skill in the art to combine all cited documents. The combination of Gelber, Adams, Kamishita, Beerse, and Betbeder does not teach or suggest each and every element of Applicants' presently claimed invention, nor provide motivation or expectation of success for the claimed invention as a whole, i.e. method of treating SARS by administering a nasal respiratory tract composition having a pH of from about 3.0 to about 5.5 to areas of the upper respiratory tract, wherein the respiratory tract composition comprises: from about 0.01% to about 10% by weight of an organic acid; from about 0.01% to about 20% by weight of a metal compound comprising a metal ion selected from the group consisting of manganese(Mg), silver (Ag), zinc (Zn), tin (Sn), iron (Fe), copper (Cu), aluminum (Al), nickel (Ni), cobalt (Co), or mixtures thereof; from about 0.01% to about 30% by weight of a mucoadhesive polymer selected from the group consisting of hydroxypropyl methylcelluloses, hydroxypropyl celluloses, methyl cellulose polymers, carboxymethyl cellulose polymers, salts of carboxymethyl cellulose, and mixtures thereof and thermoreversible polymers selected from the group consisting of poloxamers, ethylhydroxy ethylcelluloses, and mixtures thereof; wherein the composition has a viscosity of from about 1 cps to about 2000 cps.

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Accordingly, Claims 1-5, 10, and 12-16 are novel and nonobvious over the prior art of record. Reconsideration and withdrawal of the rejection on this basis are requested.

Conclusion

This response represents an earnest effort to place the present application in proper form and to distinguish the invention as claimed from the applied documents. In view of the foregoing, entry of the amendments presented herein, reconsideration of this application, and allowance of the pending claims are respectfully requested.

Respectfully submitted,

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